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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,482	03/02/2007	Masatoshi Hagiwara	6235-76051-01	3652

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,482	HAGIWARA ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5 and 12, drawn to an antiviral agent comprising an SR activity-controlling agent that controls an activity of an SR protein, wherein the agent is a substance or composition that enhances dephosphorylation of an SR protein. **Election of this group requires further election of one SR protein from claim 2, as well as one gene from claim 5, as well as one virus from claim 12, as explained below.**

Group II, claims 1, 2, 6, 7, 8, 9 and 12, drawn to an antiviral agent comprising an SR activity-controlling agent that controls an activity of an SR protein, wherein the agent is a substance that inhibits an SRPK, wherein the SRPK is an SRPK1. **Election of this group requires further election of one SR protein from claim 2, as well as one inhibitor from claim 9, as well as one virus from claim 12, as explained below.**

Group III, claims 1, 2, 6, 7, 8, 9 and 12, drawn to an antiviral agent comprising an SR activity-controlling agent that controls an activity of an SR protein, wherein the agent is a substance that inhibits an SRPK, wherein the SRPK is an SRPK2. **Election of this group requires further election of one SR protein from claim 2, as well as one inhibitor from claim 9, as well as one virus from claim 12, as explained below.**

Group IV, claims 1, 2, 10, 11 and 12, drawn to an antiviral agent comprising an SR activity-controlling agent that controls an activity of an SR protein, wherein the agent is a substance having the activity of antagonizing an SR protein. **Election of this group requires further election of one SR protein from claim 2, as well as one virus from claim 12, as explained below.**

Group V, claims 13 and 14, drawn to a method for screening an antiviral agent.

Group VI, claim 15, drawn to a method for producing antiviral agents.

Group VII, claims 16-21, drawn to an aniline derivative with the structural characteristics recited in claims 16-21.

Group VIII, claims 22 and 23, drawn to an SRPK inhibitor and an antiviral agent, each comprising the aniline derivative of claim 16.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims are directed to methods or compounds, wherein the claims recite multiple SR proteins and different types of inhibitory molecules. According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

> (A) all alternatives have a common property or activity and; (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives; or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The instant SR proteins of claim 2 are considered to be each separate inventions for the following reasons: The SR proteins of claim 2 do not meet the criteria of (A), common property or activity or (B)(1) common structure or (B)(2), art recognized class of compounds. Each of the proteins are separate and distinct, each having a distinct structure and sequence. Each member of the class cannot be substituted, one for the

other, with the expectation that the same intended result would be achieved. Further, the proteins do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the proteins is lacking and each protein claimed is considered to constitute a special technical feature.

Furthermore, claim 9 recites that the SRPK gene expression inhibitor is a miRNA, siRNA, morpholino oligo targeting an SRPK, an expression vector for the miRNA, or an expression vector for the siRNA. Each of the inhibitory molecules, miRNA, siRNA and morpholino oligos are separate and distinct, each having a distinct structure and acting via a different mechanism. The inhibitory molecules do not meet the criteria of (A), common property or activity or (B)(1) common structure or (B)(2), art recognized class of compounds. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved. Further, the inhibitory molecules do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the inhibitors is lacking and each inhibitor claimed is considered to constitute a special technical feature. Therefore, the inhibitory molecules recited in claim 9 are considered to constitute three inventions, a miRNA and an expression vector for the miRNA; a siRNA and an expression vector for the siRNA; and a morpholino oligo.

Accordingly, upon election of a group, applicant is further required to elect one SR protein and/or one inhibitory molecule, as specified in the groups listed above.

Furthermore, 37 CFR 1.475(b) states:
"An international or a national stage application containing claims to different

categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In the instant case, the instant claims do not all fall into one of the only 5 combinations of categories which can have unity of invention as defined by 37 CFR 1.475(b). The claims are directed to multiple processes comprising separate and distinct steps, as well as to separate and distinct products that are structurally distinct. That claims are directed to agents that have different functions, i.e. enhance vs. inhibit activity, as well as different structures. Since the claims are directed to multiple products as well as methods, there is no special technical feature linking the groups listed above as defined by 37 CFR 1.475(b).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of claim 5 are as follows:

HIV tat gene, an adenovirus E4-ORF4 gene, or a vaccinia virus VH1 gene.

The species of claim 12 are as follows:

A human immunodeficiency virus (HIV), severe acute respiratory syndrome (SARS), poliovirus, human rhinovirus, adult T cell leukemia virus (HTLV-I), hepatitis A, C, D, and E viruses, vaccinia virus, Japanese encephalitis virus, dengue virus, human coronavirus, Ebola virus, influenza virus, or sindbis virus, a herpes simplex virus, human adenovirus, hepatitis B virus, cytomegalovirus, EB virus, herpesvirus, human herpesvirus, smallpox virus, polyoma virus, or human papilloma virus.

Upon election of a group, as notated above, applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the genes are structurally distinct, each requiring a separate search and corresponding examination. The genes do not contain a common structural core.

Furthermore, each of the viruses has separate and distinct etiologic consideration, each requiring a separate search and corresponding examination.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755. The examiner can normally be reached on Monday-Thursday 6:30 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy H. Bowman/
Patent Examiner
Art Unit 1635